UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

APOTEX CORP., a Delaware corporation,

Plaintiff,

v.

HOSPIRA HEALTHCARE INDIA PRIVATE LIMITED, an Indian corporation; HOSPIRA, INC., a Delaware corporation,

Defendants.

CIVIL ACTION NO. 1:18-cv-04903-JMF

SECOND AMENDED COMPLAINT

JURY TRIAL REQUESTED

TABLE OF CONTENTS

Plaintiff Apotex Corp. ("Apotex") complains against Defendants Hospira Healthcare India Private Limited ("Hospira India") and Hospira, Inc. (together, "Hospira")[1] as follows:

I. NATURE OF THE CASE

1. In 2003, Apotex and Orchid Chemicals and Pharmaceuticals, Ltd. ("Orchid"), an Indian manufacturer of active pharmaceutical ingredient ("API") and finished pharmaceutical Products, entered into a long-term drug co-development and joint commercialization agreement (the "Agreement"). Under the Agreement, Apotex and Orchid agreed to share the profits derived from developing, manufacturing, and distributing a variety of injectable drug Products, including, without limitation: cefazolin, ceftriaxone, cefoxitin, cefepime, and piperacillin-tazobactam ("pip/taz") (collectively, the "Shared Profit Drugs" or the "Products"). To facilitate this goal, Apotex agreed to purchase the Shared Profit Drugs exclusively from Orchid. Orchid, in turn, was obligated to supply Apotex with all of its requirements for these Products. For approximately six years, Apotex and Orchid's co-venture was successful and operated consistent with the Agreement.

2. Then, in 2010 Hospira acquired the business of Orchid relevant here and after that acquisition succeeded to Orchid's interests and obligations under the Agreement. However, unlike Orchid, which did not sell pharmaceutical Products in the United States and was not a competitor of Apotex, Hospira did compete with Apotex in the United States pharmaceuticals market and soon thereafter was in stark breach of its supply and other obligations under the Agreement.

[1] Apotex continues to investigate whether other persons or entities besides Hospira, Inc. and Hospira India participated in the wrongdoing at issue and reserves the right to seek leave to add additional defendants if such participation is discovered.

3. But Hospira did much more than simply breach the Agreement by failing to supply Apotex with its requirements of the Shared Profit Drugs. It used the Agreement as a means to undermine Apotex's ability to compete against it and gain an unfair competitive advantage.

4. Hospira repeatedly lied to Apotex. After cutting off Apotex's supplies of essential Products under the Agreement, Hospira lied to Apotex about the causes of the supply disruptions, about the capacity of its manufacturing facilities, about what Products it could manufacture at its IKKT facility and about its ability to identify alternative sources of supplies of the Shared Profit Drugs. It failed to disclose the fact that it was misusing Apotex's confidential information to take customers from Apotex. Hospira falsely led Apotex to believe that it was committed to the parties' Agreement to share profits derived from the development and commercialization of the Shared Profit Drugs when it was instead using its breaches of the Agreement as a means to capture for itself all of the very profits the parties had agreed to share.

5. To take advantage of the demand it created by breaching its supply obligations under the Agreement, Hospira misappropriated Apotex's confidential information and used this to target and capture Apotex's frustrated customers—who were frustrated because Hospira's breaches meant that Apotex could not supply them, exactly what Hospira intended. Hospira then exploited Apotex's inability to supply its customers—by selling to those same customers Hospira's own versions of certain of the Shared Profit Drugs in place of Apotex's drugs, priced the same or very near the prices Apotex had offered in the market. Of course, Hospira only knew these prices because Apotex was obligated to share that confidential information with Hospira in order to calculate the share of Apotex' profits to which Hospira was entitled under the

Agreement. Additionally, because only Hospira knew its actual cost to manufacture the Shared Profit Drugs, it was able to undercut Apotex's prices and keep the entire profit for itself.

6. A glaring example of Hospira's tortious conduct is its marketing of Maxipime™. Maxipime™ is the brand name version of the same cefepime product Hospira supplied to Apotex. Orchid did not manufacture the brand version of the cefepime product. Nor did Hospira when it first took over the Agreement. Yet, in or about 2012, Hospira bought Maxipime™. Hospira did so to bypass the Agreement's specific restrictions about manufacturing competing generic products at the IKKT facility. While the Agreement as amended by a novation entered into between Apotex and Hospira (the "Novation"),[2] does not prohibit Hospira from manufacturing brand products at the IKKT facility, it requires Hospira to prioritize production of cefepime for Apotex at its manufacturing facilities over production of Maxipime™ (or any other Hospira product) and obligates Hospira to supply Apotex with all of its requirements for cefepime. Moreover, when Hospira is unable to manufacture sufficient quantities of cefepime (or other Products) to meet Apotex's requirements, the Agreement requires Hospira to obtain alternative sources of supply from third parties. Yet after purchasing Maxipime™, Hospira disregarded all of these obligations. It simply stopped producing sufficient quantities of Apotex's drug cefepime at its IKKT facility, telling Apotex it had technical and supply issues that prevented it from manufacturing the drug in quantities sufficient to satisfy Apotex's requirements. At the same time, Hospira continued to manufacture Maxipime™, its rival drug, at the same facility. Then, after leaving Apotex unable to fill its customers' orders for cefepime, Hospira went to Apotex's customers and, armed with Apotex's confidential average price, priced

[2] The "Novation" is formally called the "Novation and Amendment No. 6 to Development, Manufacturing, Supply and Commercialization Agreement."

Maxipime™ near this price to steal these customers for its own drug. For example, one Apotex customer, Novation Pharmaceuticals Inc. ("NPI"), advised Apotex that Hospira had approached it offering to sell it Maxipime™ at a price just above Apotex's prices. Throughout this period, Hospira continuously and consistently was months late in processing Apotex's orders, and even when it processed orders, consistently failed to supply Apotex with the amount of drugs it had ordered and needed to serve its clients. The result: Apotex's sales plummeted while Hospira's sales of competing Products skyrocketed. In no time, Hospira increased its market share of Maxipime™ ten-fold, while Apotex, which had been the market leader, saw its share dwindle. Hospira thus captured for itself tens of millions of dollars of profits that would otherwise have been shared by the parties under the Agreement, while at the same time damaging Apotex's reputation and relationships with customers.

7. Another example of Hospira's tortious overreach is seen with pip/taz. For years Hospira failed to fulfill Apotex's orders for pip/taz while continuing to source pip/taz to sell its own rival products. After 2016, Hospira simply stopped filling these orders and presently sits on 55 open orders for pip/taz (and other Products). Hospira could have fulfilled its obligations to Apotex by providing Apotex with the pip/taz it sourced for itself for resale, but refused to do so, despite its duty to prioritize Apotex's needs. While Apotex has another source for certain of the strengths of pip/taz, it does not for other strengths. So Hospira's failure-to-supply has effectively removed Apotex as a generic competitor in these strengths, enabling Hospira (and its parent Pfizer) to grab market share that should instead have gone to Apotex. The result: in 2018 Pfizer, Hospira's parent, sold $393 million of pip/taz products, while Apotex sold $774,823.

8. Now Hospira attempts to administer the coup de grace to its rival by eliminating Apotex's ability to obtain the Products, first by refusing to honor its supply obligations, and

second by alleging that Apotex's efforts to mitigate its damages is a breach of the very contract Hospira refuses to honor. On January 8, 2019, Hospira announced through a press release that it intended to close its IKKT facility in India—the only facility at which it manufactures Products for Apotex. Hospira's decision was made at its own election and unilaterally. The industry website, www.fiercepharma.com reported Pfizer as saying that "it makes no sense to continue operations due to the very significant loss of product demand."[3] But this statement just evidences Hospira's utter disregard for its ongoing contractual obligation to Apotex, which continues to demand and be owed Product. Shortly after its press release, in terse communications with Apotex and its counsel on January 8 and 9, 2019, Hospira informed Apotex of its decision, without addressing its obligations under the Agreement or the impact its decision would have on Apotex. And, even though the Agreement continues between the parties, in the months since the announcement of the closing, Hospira has yet to acknowledge its ongoing commitment to supply future product. It has not identified any other Hospira manufacturing facility which is capable of producing these Products or to which it will shift manufacturing. Hospira has not agreed to Apotex's request that it obtain Products through third party sources and supply those Products to Apotex, although the Agreement requires this. And while claiming – for months – that it is investigating the possibility of third party sources, Hospira has identified no such source nor provided any detail of anything it is doing to accomplish this. Moreover, there are currently 55 open purchase orders Apotex has submitted to Hospira. These have been unfilled for some time, but while IKKT is open there is at least a possibility for future performance. With IKKT closing, that possibility disappears and Apotex

[3] *See* https://www.fiercepharma.com/manufacturing/pfizer-to-close-2-legacy-hospira-plants-India-putting-1-700-jobs-jeopardy.

has no source for certain of these drugs or, in the case of pip/taz, for certain strengths of the drugs. Likewise, for other existing purchase orders, Hospira purported to fill the order and ship products to Apotex, but then directed Apotex not to distribute these Products because they were subject to an FDA recall that was imposed solely because of Hospira's performance failures. Hospira has yet to supply replacement product for these orders, making them effectively unfilled as well. Hospira has likewise refused to acknowledge its obligation to fill these open orders or explain how it plans to do so.

9. After years of waiting for Products, Apotex was able to source certain Products from Qilu Pharmaceuticals Co., Ltd. ("Qilu"). However, it has not been able to source all Products, including certain strengths of pip/taz, as well as cefoxitin Products. This means that Apotex will have to cease selling these drugs. And Hospira has tried to threaten Apotex as to the Products it has been able to source through Qilu, asserting that this is a "Gross Breach" of the Agreement,[4] even though Hospira has ceased manufacturing and supplying these Products to Apotex, a state of affairs Hospira's voluntary closure of IKKT now makes permanent. Thus, the IKKT closure is plainly the latest in a series of efforts by Hospira to eliminate competition in the markets for these Products.

10. Parties that venture together under long-term agreements to share profits owe each other special duties arising out of their commercial arrangement. When parties provide confidential information under a contract they owe each other an additional duty to use that information solely for purposes of the contract. Hospira cavalierly ignored these special duties.

[4] Hospira has even made this argument in submissions to the Court. *See* Hospira's Motion To Dismiss Apotex's First Amended Complaint dated December 4, 2018 (Doc. 38) at 1,4.

Through misappropriation and deception, it willfully breached the contract in a manner that was intended both to injure Apotex and give Hospira an unfair competitive advantage. As a result of Hospira's tortious conduct, Apotex incurred damages distinct from its contract damages, which Apotex seeks to recover here, including damage to its reputation and goodwill with its customers.

11. As described more fully below, Hospira materially breached the Agreement by: (a) systematically and continuously failing to meet its drug supply obligations; (b) failing to prioritize manufacture of Shared Profit Drugs for Apotex at manufacturing plants it operated; (c) failing to find replacement Products for Apotex when Hospira could not fill Apotex's purchase orders; (d) wrongfully entering into contracts, commitments or agreements that impaired or inhibited its ability to perform its obligations under the Agreement; e) failing to pay Apotex royalties on sales of cefazolin Products to a limited group of customers defined as "Permitted Customers" under the Agreement and failing to adhere to the supply price to these customers that Orchid (and later Hospira) had promised; (f) wrongfully selling, offering for sale, manufacturing, supplying or otherwise providing cephalosporin drug Products and/or their API to third parties in violation of the exclusivity and non-compete provisions of the parties' Agreement; and (g) now shuttering the sole plant where Shared Profit Products have been manufactured.

12. Hospira's misconduct, including its tactics to gain market leadership of cefepime and to eliminate Apotex as a rival in other drugs, including ceftriaxone and cefazolin, also constitutes unlawful monopolization and attempted monopolization in violation of Section 2 of the Sherman Act. 15 U.S.C §2.

13. In addition, Hospira's course of conduct defrauded Apotex, and tortiously interfered with Apotex's existing and prospective business relationships. The misappropriation

and misuse of Apotex's confidential information also constituted unfair competition. This conduct also violated the Florida Unfair and Deceptive Trade Practices Act ("FDUTPA"), Fla. Stat. §§ 501.201 *et seq.* To the extent, Hospira profited from anticompetitive acts outside the Agreement, it was unjustly enriched.

14. As a result, Apotex seeks to recover (a) compensatory and special damages, including, but not limited to, lost profits, consequential damages, restitution, and disgorgement of Hospira's profits; (b) exemplary and/or punitive damages; (c) all damages and relief available under New York common law; and (d) all damages and relief available under the FDUTPA, including but not limited to attorneys' fees and costs; and (e) treble damages, costs and attorneys' fees for Hospira's antitrust violations.

II. PARTIES

15. Apotex is a Delaware corporation, which is doing business in the State of New York and has its principal place of business at 2400 North Commerce Parkway, Suite 400, Weston, Florida 33326.

16. Upon publicly available information and belief, Hospira India is an Indian corporation, which is doing business in the State of New York and has its principal place of business at SIPCOT Industrial Park, Irungattukottai, Sriperumburdur - 602 105, Tamil Nadu, India.

17. Hospira, Inc. is a Delaware corporation with its principal place of business at 275 North Field Drive, Lake Forest, Illinois 60045. Upon information and belief, Pfizer Inc. acquired Hospira in September 2015.

III. JURISDICTION AND VENUE

18. This Court has original jurisdiction pursuant to 28 U.S.C. §§ 1331, 1337, because Apotex brings claims under the Sherman Act, a federal statute. Jurisdiction over non-federal claim is appropriately exercised under 28 U.S.C. § 1367.

19. Venue and personal jurisdiction are proper in the Southern District of New York because the parties, by agreement, have submitted to such jurisdiction and venue and have waived all claims of an inconvenient forum.

IV. FACTS COMMON TO ALL COUNTS

A. Overview

20. Apotex distributes pharmaceutical Products in the United States. Apotex and Orchid entered into the Agreement in or about June 2, 2003, to co-develop and jointly commercialize in the U.S. market generic versions of the Shared Profit Products. The Agreement anticipated a long-term relationship between the parties that would govern multiple different drug categories. It anticipated that Orchid (and Hospira as its successor) would play an essential role at each stage of the development and commercialization of each of these drugs. Although Orchid/Hospira was primarily responsible for executing these development activities, Apotex shared the cost associated with them. Apotex, in turn, was responsible for commercializing generic versions of the drug Products in the U.S. market and was required to purchase all its requirements for the Products solely from Orchid/Hospira.

21. The partnership between Orchid and Apotex succeeded for six years. Apotex successfully commercialized in the U.S. cefazolin, ceftriaxone, cefoxitin, cefepime, and pip/taz. Orchid generally supplied Apotex with adequate quantities of these Products to meet market demand. As required by the Agreement, Apotex reported its confidential pricing and sales

information (including gross revenues, costs, and net profits) to Orchid, and the parties split the profits.

22. In 2010, Hospira purchased Orchid's generic injectable business, including IKKT – the manufacturing plant at which Orchid produced the Products subject to the Agreement. After this acquisition, Hospira succeeded to the obligations of Orchid by entering into the Novation on or about March 23, 2010. Unlike Orchid, which did not sell finished drug Products in the United States market, Hospira was at the time of the Novation and is today engaged in the business of selling injectable generic pharmaceutical Products in the United States and at all relevant times has been therefore an existing Apotex competitor. Recognizing this, and as part of the consideration for its agreement to permit Hospira India, its competitor, to assume, pursuant to the terms of the Novation, Orchid's rights under the Agreement, Apotex obtained certain additional conditions amending the terms of the Agreement. In particular, Hospira India expressly agreed that Apotex would be contractually entitled to recover as "liquidated damages" any profits lost as a result of, among other things, Hospira India's failure to meet its supply obligations under the Agreement.

23. Hospira proved to have little interest in splitting profits with Apotex. Instead, Hospira embarked on a plan to capture profits solely for itself by diverting sales from Apotex. Hospira crippled Apotex's ability to commercialize the relevant Products and captured for itself the sales that Apotex would otherwise have made.

24. First, blaming manufacturing difficulties, Hospira sabotaged Apotex's efforts to commercialize the Shared Profit Drugs in the U.S. by systematically and continuously failing to deliver the drug Products Apotex ordered, creating a market shortage that U.S. customers blamed on Apotex. Next, Hospira converted Apotex's confidential business information and filled the

market demand it had created by selling competing Products to Apotex's U.S. customers at prices near the prices offered by Apotex. Hospira was aided by the fact that only it (and not Apotex) knew the true cost of goods for the Products Hospira was obligated to supply to Apotex. Hospira sourced its competing Products in one of two ways, both of which violated Apotex's rights under the Agreement. Some Products were manufactured at IKKT – the very facility that Hospira claimed was crippled by technical manufacturing issues – in breach of Hospira's obligation to prioritize the manufacture of the shared Profit Drugs for Apotex over the requirements of any other entity (including Hospira itself). Other Products were sourced from third parties and sold by Hospira in competition with Apotex despite that Hospira was contractually obligated to Apotex to mitigate its manufacturing problems by sourcing product from third parties to fill Apotex's otherwise unfilled orders. Hospira's scheme devastated Apotex's U.S. market share in the relevant markets and diverted to Hospira hundreds of millions of dollars of profits that should have been shared between the parties under the terms of the Agreement. Now Hospira is closing IKKT entirely and has made no arrangement to supply Apotex with the Products it has already ordered or which it has a right to order under the Agreement in the future.

B. The Generic Drug Industry and Market

1. Generic Drugs Are A Low Cost Competitive Alternative To Brand Drugs

25. In the United States, pharmaceutical Products generally are divided into two categories: brand Products and generic Products. These Products may either be self-administered drugs ("SADs"), (*e.g.*, oral drugs, suppositories, and topical medications self-administered by the patient); or physician-administered drugs ("PADs") (*e.g.*, injectable and non-

injectable drugs typically administered by healthcare professionals ("HCPs") in physicians' offices, clinics, hospitals, or laboratories.)

26. To obtain approval for the sale of new brand Products, drug manufacturers must submit a new drug application ("NDA") to the FDA. The application must be supported by data demonstrating the drug's safety and efficacy for its intended use(s).

27. An approved brand drug may receive patent protection on its chemical formulation or manufacturing process and is often marketed under a proprietary, trademark-protected name. During the life of their patents, brand drugs are called "single-source" drugs because only the company that holds the patent may lawfully produce and sell them.

28. After a brand drug's patent(s) has expired, generic copies of the exact chemical formulation usually become available to consumers at much lower cost. Such drugs are referred to as generic or "multiple-source" drugs.

29. Generic drugs, by design, obtain regulatory approval under a shorter process than brand drugs. Generic manufacturers can submit an abbreviated new drug application ("ANDA") to the FDA, which relies on the safety and efficacy evidence previously submitted by the manufacturer of the corresponding brand product. To gain FDA approval, a generic drug must have the same API, strength, dosage form, route of administration, and intended use(s) as its brand counterpart, and it must meet the same quality and manufacturing standards. The process by which generic drugs obtain FDA approval is described in the Federal Trade Commission's ("FTC") study titled Generic Drug Entry Prior to Patent Expiration: An FTC Study (FTC July 2002) [the "Generic Drug Entry Study"].[5]

[5] *Available at* https://www.ftc.gov/sites/default/files/documents/reports/generic-drug-entry-prior-patent-expiration-ftc-study/genericdrugstudy_0.pdf (last accessed on May 21, 2018).

2. Generic Drugs Promote Price Competition And Benefits For Consumers

30. Competition in the U.S. drug market varies significantly depending on whether a brand drug faces competition from generic drugs. Manufacturers selling brand drugs often enjoy temporary market monopoly power, which enables them to command large profits by charging consumers and HCPs prices above those charged in non-monopolistic (or "mature") markets.

31. Manufacturers typically market their brand Products by promoting the benefits directly to physicians, *i.e.*, "detailing," and, in some cases, through direct-to-consumer advertising. In this way, manufacturers educate prescribers and patients about the therapeutic qualities of their brand Products, including the indications for which they are approved.

32. Manufacturers often sell brand drugs to drug wholesalers or distributors. Retail pharmacies usually acquire brand drug Products through the wholesalers and distributors that purchase from the manufacturer and not directly from the manufacturer itself.

33. The expiration of a brand drug's patent frequently prompts more than one generic copy to enter the market. The central purpose of the Drug Price Competition and Patent Term Restoration Act of 1984 (commonly referred to as the "Hatch-Waxman Act") is to promote generic competition and get generics into the hands of patients on the earliest date possible under the law.[6] The Hatch-Waxman Act reconfigured the existing generic drug approval process to speed up generic drug introduction to the market. The legislation encouraged generic entry by creating a 180-day marketing exclusivity period for the first generic firm to do so.

34. As the FTC notes in its Generic Drug Entry Study, generic drugs are generally far less expensive than brand Products and the market entry of generic drugs can result in large

[6] *See generally*, *Generic Drug Entry Study* at 3-8 (discussing Hatch-Waxman Act).

savings to consumers.[7] Indeed, the FTC found that the price of generic pharmaceuticals is approximately half that of brand drugs.[8] One of the reasons for this market phenomenon is that, unlike brand companies, generic manufacturers do not detail physicians or market directly to consumers. Instead, generic drugs that are "AB" rated as therapeutically equivalent to a particular brand drug, with certain limited exceptions, are automatically substituted and dispensed to patients who are prescribed the reference brand drug.

35. Indeed, all states and the District of Columbia have what are referred to as generic substitution laws which promote the use of generic Products by requiring or authorizing a pharmacist to fill a patient's prescription with a generic product. Therefore, a generic alternative is available for a brand drug, that generic drug will be dispensed to a patient instead of a brand drug even where the brand drug is prescribed. Because of these laws,[9] once generic products enter the market, the brand products lose significant market share to the generics at a precipitous rate, a phenomenon that is referred to as the "generic cliff" or waterfall.[10] The loss in the brand product's market share is captured by the generic market participants.

36. Because multiple manufacturers sell nearly identical generic versions of the same product, they distinguish themselves and compete against one another for market share based on price, consistency of supply and quality.

---

[7] Generic Drug Entry Study at 9.

[8] *Id.*

[9] *Improving Health Care: A Dose of Competition* at 12-13(FTC, DOJ July 2004) ("Because generic drugs are substantially less expensive than their brand-name counterparts, generic substitution lowers prescription drug costs."), *available at* https://www.ftc.gov/sites/default/files/documents/reports/improving-health-care-dose-competition-report-federal-trade-commission-and-department-justice/040723healthcarerpt.pdf (last accessed on May 21, 2018).

[10] As the FTC notes, "generic entrants gain significant market share at the expense of their rival brand name drug companies after their entry." *Generic Drug Entry Study* at 9.

3. Apotex Sells Generic Pharmaceuticals Which Compete With Brands

37. Apotex is an innovative global research and technology leader in generic pharmaceuticals.

38. Apotex sells a variety of SADs and PADs, including specialty and injectable Products. Among these are generic antibiotic and antibacterial injectable Products, including cephalosporins. These Products belong to therapeutic classes in which generic competition is robust.

39. Apotex competes with many manufacturers producing virtually identical drugs. Apotex differentiates itself in several ways, including price, quality, breadth of portfolio, and consistency of supply.

40. Consistency of supply is an especially important factor in the generic pharmaceutical market, as Apotex is required to compensate many of its customers for any considerable delay or failure to supply Products under the terms of its customer agreements.

41. To timely meet customer demand, Apotex periodically contracts with third parties engaged in the development and manufacture of API and finished dosage forms of drugs in Apotex's product pipeline.

C. Under The Agreement, Orchid Agrees To Supply API And Finished Products Exclusively To Apotex

42. On or about June 2, 2003, Apotex and Orchid entered into the Agreement. The Agreement expressly states that the parties' overarching objective was to "pool[] the respective costs of development, manufacture and marketing of Products [injectable cephalosporins identified in Exhibit C(1) and C(2) of the Agreement (hereinafter, the "Products")]," and "shar[e] the profits out of revenues from sale of such Products in the Territory." *Id*. at 1.

43. The Agreement provided that Orchid would undertake essential steps at each stage of the development, manufacture and commercialization of Apotex's drugs. Orchid agreed, inter alia, to: (1) "conduct development and testing work on the API and the Products;" (2) to obtain FDA approval for the Products; (iii) "to be a source of intermediate and starter components . . . for the manufacture of [API] . . . and to be a source for such other finishing ingredients, if any, and final containers necessary to manufacture the API into Products . . . ;" (iv) to be a manufacturer and source of the Products;" and (v) "to be a supplier to Apotex of Products." Agreement at 1. Apotex, meanwhile, agreed to provide consulting services to Orchid and to commercialize the Products in the United States. *See id.* § 1.36. at 1.

44. Article 3 of the Agreement describes Orchid's product development obligations. In consultation with Apotex, Orchid was required to perform all activities related to the development of the Products, including conducting tests, studies and clinical trials necessary to the preparation and filing of an ANDA or to meet other regulatory requirements. Agreement § 3.1(b). Under the Agreement, Orchid was responsible for filing, in its own name, any ANDA or other regulatory filings and to consult and jointly agree with Apotex regarding the timing of any such filings. *Id.* § 3.3(a). The Agreement also provides for Orchid and Apotex to negotiate the joint development or marketing of any additional therapeutic indications identified for the Products during the term of the Agreement. *Id.* § 3.6(a).

45. Article 6 of the Agreement governed the marketing and commercialization of Products and profit sharing from commercial sales in the Territory. Section 6.1 incorporated by reference Exhibit E to the Agreement, which consists of Apotex Projected Marketing & Commercialization Plans (the "Plans") for each Product. The Plans included: 1) an anticipated launch date; 2) sales projections, 3) the Apotex net price per unit, and 4) other information,

including commercially sensitive pricing information. Under Article 6.2 of the Agreement, Apotex is required to provide Hospira with quarterly statements used to support Apotex's calculation of the profit-sharing payment owed to it. Each of these quarterly statements must include the following confidential information: "the total units of Products sold, associated net sales price (per Product), and Operating Profit." *Id.* § 6.2 (b).

46. The parties identified the Products subject to the Agreement on Exhibits C(1) and C(2) of the Agreement; these included: cefazolin, ceftriaxone, cefotaxime, ceftazidime, cefoxitin, cefotetan, cefepime, and pip/taz.[11] The Agreement's term "commence[d] upon the Effective Date," *i.e.*, June 2, 2003, and "continue[d] . . . with respect to each Product Family for ten years after the Actual Launch Date," as defined in § 5.1(b). *See id.* § 12.1(a).

47. Orchid contracted to supply Apotex exclusively with the API and finished dosage form for each drug in each Product Family. Specifically, Orchid agreed "to sell, offer for sale, lease, manufacture, supply and/or test the Products listed in Exhibit C(1) and C(2) of this Agreement solely and exclusively to Apotex for sales and marketing in the Territory in accordance with the terms and conditions of this Agreement." Agreement § 7.1(a). With regard to API for the Exhibit C(1) drugs, the Agreement provided:

> During the Term Orchid shall not sell the API used in such Products of Exhibit C(1) for use in any Drug Product that is the same as any Product in Exhibit C(1) to any third party in the Territory or to any third party that Orchid knows or reasonably believes is selling such API into the Territory[12] for use in any Drug Product that is the same as any Product in Exhibit C(1).

[11] Exhibit C(1) and C(2) to the Agreement and Amendment No. 1 (as defined below) describe this product only as tazobactam. The drug is described as "piperacillim-tazobactum" for the first time in the Novation (as defined below).

[12] "Territory" is defined to include "the United States and its respective territories, possessions and military institutions." Agreement § 1.36.

See id. § 7.1(b)(i) (emphasis added). Apotex insisted on this obligation because Apotex shared in the development costs of the Products and therefore wanted to make sure that Orchid would not later compete with it, either directly (selling it itself) or indirectly (supplying competitors).

48. Under § 7.1(b)(ii), Orchid could supply API for Exhibit C(2) drugs to others but only "to those specific third parties with whom Orchid has arrangements to supply prior to the [Agreement's] Effective Date." (emphasis in original). Orchid warranted that "no contracts, commitments or agreements of any nature exist, and Orchid covenants that none will be entered into during the Term, that impair or inhibit the ability of Orchid to perform its obligations hereunder." Agreement § 14.2(a).

49. In addition to agreeing it would exclusively supply Product to Apotex,

> [d]uring the Term, Orchid agree[d] that it will not, nor will it permit or cause its Affiliates or any third party to, enter into any agreement or arrangement to exploit, including without limitation to manufacture, sell, offer for sale or commercialize, in the Territory any of the Products supplied to Apotex hereunder; provided that this shall not apply to API used in Products listed in Exhibit C(2) of this Agreement as per Section 7.1(b)(ii).

Agreement § 7.3(a).

50. Article 7's limitations applied to any "Product," defined as "a finished dosage form of a Drug Product that (i) is listed in Exhibit C1 or C2 of th[e] Agreement; (ii) is the same as a Listed Drug as defined under 21 C.F.R. § 314.3 included in 'Approved Drug Products with Therapeutic Equivalence Evaluations,' (the 'Orange Book') current as of the Effective Date and (iii) is a Generic Product." Agreement § 1.27.

D. Despite Amendments To The Agreement, The Parties' Shared Objectives To Jointly Commercialize Apotex's Products Remains In Place

51. Between June 2003 and January 2010, Orchid and Apotex amended the agreement on five separate occasions.

52. On March 6, 2006, Apotex and Orchid executed an Amended and Restated Development, Manufacturing, Supply and Commercialization Agreement (hereinafter, "Amendment No. 1"). The purpose of Amendment No. 1 was to "amend and restate some of the provisions of the [June 2003] Agreement," primarily those reflecting and relating to the parties' profit sharing and payment of transfer prices. *See generally*, Amendment No. 1 at 1, §§ 5.7, 6.2, 6.3. With the exception of one non-material revision to § 5.12(b), Amendment No. 1 did not change the following provisions of the Agreement, leaving unaffected the rights and obligations arising thereunder: § 1.27 ("Product"); § 1.36 ("Territory"); § 5.12(a) (Notice of Delay); § 5.12(b) (Remedy; Offset); § 5.13 (Minimum Sales Obligations Not Applicable); § 7.1 (Exclusivity); § 7.3 (Non-compete); § 12.2(b) (Arbitration); § 12.2(c)(i)-(iv) ("Gross Breach"); Article 14 (Orchid General Warranties); Article 15 (Covenants by Orchid); § 19.8 (Governing Law); § 19.9(a) (i) ("A Party is not required to submit Gross Breaches to arbitration."); and § 19.9(b) (Jurisdiction).

53. Amendment No. 2 was executed on or about November 8, 2006. In Amendment No. 2, the parties acknowledged that Orchid had been selling cefazolin injectable Products to "various third parties for use in the Territory." Amendment No. 2 at unnumbered page 1. Orchid and Apotex amended the Agreement to authorize sales of cefazolin injectable Products only to a list of "Permitted Customers." Orchid agreed to pay royalties to Apotex in the amount of 5 percent of the "Total Supply Price" (as defined in Amendment No. 2) to the Permitted Customers. Amendment No. 2 at § 6. In addition, Orchid agreed to sell cefazolin injectable Products to Permitted Customers for an amount at least 30 percent higher than the transfer price it charged Apotex for such Products. *Id.* at § 4. Finally, Orchid agreed that it would give priority to Apotex over any of the Permitted Customers. *Id.* at § 5. This concept of priority

meant that if Orchid had unfilled orders for cefazolin Products from both Apotex and any Permitted Customers and was unable to manufacture and supply sufficient quantities of such Products to fill all outstanding orders, Orchid was required to allocate all supply of any such Products first to Apotex until all outstanding Apotex orders had been filled before allocating any supply to any of the Permitted Customers.

54. The parties executed Amendment No. 3 on or about February 27, 2007. Amendment No. 3 largely focused on the launch of generic cefepime. The parties agreed to jointly defend any patent lawsuit related to the launch of the product. In addition, Apotex agreed to pay Orchid $1.9 million in connection with the development costs associated with the development of generic cefepime. All other material terms remained unchanged.

55. On or about May 4, 2007, the parties entered into Amendment No. 4. The amendment made no changes to the Agreement that are material to this dispute.

56. On or about December 4, 2009, Orchid and Apotex entered into Amendment No. 5. Amendment No. 5 dealt primarily with the pip/taz product. Pursuant to Amendment No. 5, Apotex agreed to pay Orchid $255,000 (fully 50 percent) of unforeseen costs incurred by Orchid in connection with the development and regulatory approval of the product. In addition, the parties agreed to split legal fees incurred in connection with pursuit of the product. All other material terms remained unchanged.

E. Through The Novation and Amendment No. 6, Hospira India Succeeds To Orchid's Obligations Under The Agreement As To The Co-Development, Manufacture And Joint Commercialization of Apotex's Products

57. Upon publicly available information and belief, Hospira India acquired Orchid's generic injectable finished dosage form pharmaceuticals business, including the manufacturing plant at IKKT, in 2010.

58. On or about March 23, 2010, Apotex, Orchid, and Hospira India executed the Novation. The Novation substituted Hospira India for Orchid "in all the obligations of Orchid under the Agreement as though Hospira were the signatory thereto and agree[d] to perform all obligations of Orchid under the Agreement[.]" Novation § 1(A)(i). It stated that, "[e]xcept as amended by this Amendment, the terms and conditions of the Agreement shall remain in full force and effect." Novation § 1(M)10.

59. The Novation establishes that, like Orchid, Hospira India will "solely and exclusively manufacture the Products listed in Exhibit C(1) and C(2) of this Agreement . . . for Apotex for marketing and sale in the Territory." Novation § 1(I). And, like Orchid,

> Hospira [] agree[d] that it will not, nor will it permit or cause its Affiliates or any third party, other than Apotex, to enter into any agreement or arrangement to sell or offer for sale in the Territory any Products listed in Exhibit C(1) or C(2) which were manufactured by Hospira [] and/or its Affiliates at IKKT [*i.e.*, Hospira's facility in Irungattukottai, India] or any other facility or location owned or leased by Hospira [] and/or its Affiliates.

Novation § 1(J). The priority provisions applicable solely to cefazolin and originally included in Amendment No. 2 were expanded to apply to all Products under the Agreement. Thus, if Hospira India became unable to supply any Product in accordance with its obligations, Hospira India was required to provide replacement product from a third-party source. Novation § 1(H).

60. Hospira also agreed in the Novation that Apotex's agreement to solely and exclusively buy Products from Hospira and to not develop, source or otherwise buy or obtain API for the Products during the Term of the Agreement would be subject "to the compliance of Hospira India and its Affiliates with the supply price and royalty provisions set forth" in Amendment No. 2. (Novation §1(I)).

61. In the Novation, the parties further agreed that Apotex shall be entitled to lost profits in the form of liquidated damages caused by Hospira India's inability to supply Product

as required by the Agreement. Apotex is also entitled to recover from Hospira India any monetary penalties that Apotex is assessed by its customers as a result of Hospira India's inability to supply Products. Section 1(H) of the Novation states in pertinent part:

> In the event that Hospira [] is unable to supply Product in accordance with this Agreement then Apotex shall, in its sole discretion, be entitled to (i) require Hospira [] to provide replacement product from a third party source (any incremental amount above the Transfer Price to be at Hospira []'s sole cost); and (ii) collect liquidated damages from Hospira [] equal to the average historical profit split levels (calculated from the previous three (3) months) for the undelivered quantities of Products for so long as such inability to supply exists, provided that Apotex is in compliance with all of its obligations under this Agreement. [I]f Apotex is assessed penalties under a contract with a third party as a result of Hospira[]'s inability to deliver Product, then Apotex may either, in its discretion but upon notice to Hospira [], deduct the amount of the penalty from Hospira[]'s share of the Net Product Sale Price or bill Hospira [] (and Hospira [] shall promptly pay) the amount of such penalty . . . .

62. Hospira India further agreed,

> during the Term, so long as Orchid is the sole API supplier to Hospira [] and its Affiliates for the Products in Exhibit C(1) and C(2), Orchid shall not sell the API used in such Products for use in any Drug Product that is the same as any Product in Exhibit C(1) or C(2) to any third party in the Territory or to any third party that Orchid knows or reasonably believes is selling such API into the Territory for use in any Drug Product that is the same as any Product in Exhibit C(1) or C(2)[.]

Novation § 5.

63. Thus, subject to certain limited exceptions,[13] Hospira India could not compete with Apotex with respect to the following product families:

- ceftriaxone;
- cefotaxime;
- ceftazidime;

[13] The Novation maintained Hospira India's right to supply Existing Competing Products (consisting of three specific cefazolin Products) to a List of Permitted Customers which included Sandoz, Watson, Cura, Ranbaxy and Hospira. Novation § 1(I). Maxipeme™ was not among these Products.

- cefoxitin;
- cefotetan;
- cefepime; and
- pip/taz.

64. The Novation left intact and did not amend § 14.2(a) of the Agreement, pursuant to which Hospira India (like Orchid) agreed and warranted, without qualification, that "no contracts, commitments or agreements of any nature exist" and "that none will be entered into during the Term, that impair or inhibit the ability of [Hospira] to perform its obligations hereunder." Agreement § 14.2(a).

F. Hospira Systematically and Continuously Breaches Its Supply Obligations

65. As required by the Agreement, Apotex regularly provided Hospira (and Orchid before it) with rolling forecasts and purchase order forms identifying each Product by name, vial size, Product Family, market, and other information.

66. Between 2003 (when Orchid and Apotex entered the Agreement) and 2010 (when Hospira India succeeded to Orchid's obligations under the Agreement), Orchid largely met its contractual obligations to supply Apotex's requirements for the Products.

67. After Hospira India succeeded to Orchid's obligations under the Agreement, however, Apotex began to experience supply problems relating to one or more of the Products.

68. At first these problems were episodic.

69. Beginning in 2012, the supply problems intensified. From that time forward, Hospira repeatedly and continuously failed to satisfy its obligations under the Agreement to timely supply conforming Products to Apotex.

70. As set forth in detail below, Hospira's supply failures were systematic and pervasive. Hospira willfully and intentionally improperly performed its contract in a manner calculated to drastically decrease Hospira's competitive position to Hospira's own substantial benefit.

71. Hospira consistently failed to deliver Products to Apotex on time, and many of its deliveries failed to include the amount of Product ordered. For purchase orders with requested delivery dates in 2012, for example, Hospira India delivered Product on time for only 1 of the 58 purchase orders that Apotex submitted. Two of the purchase orders were fulfilled almost 15 months late, that is, more than one year after the specified delivery date.[14] Hospira India supplied less than the required amount of Product for 7 of Apotex's purchase orders.[15] A small sample of these failures is illustrated in the table below:

Purchase Order No. / Product	Quantity Required	Quantity Received	Delivery Date Required	Delivery Date Received
4500389606 / cefepime inj 1g 10x20ml	6,650	5,976	9/30/2012	11/2/2012
4500395417 / cefoxitin inj 10g 10x100ml	525	435	12/3/2012	4/18/2013
4500389615 / ceftriaxone inj 250mg 10x10ml	4,750	4,050	10/30/2012	12/12/2012

72. The same pattern continued in 2013. Apotex submitted 384 purchase orders for Products to be delivered by Hospira India in 2013. Hospira India failed to timely deliver Product

[14] *See, e.g.*, Purchase Order Nos. 4500398464 (Product delivered 447 days late), 4500398464 (Product delivered 402 days late). The collection of Purchase Orders is attached hereto as Exhibit 1.

[15] *See, e.g.*, Purchase Order Nos. 4500389606 (shortfall of 674 units), 4500389615 (shortfall of 700 units), 4500389620 (shortfall of 589 units), Ex. 1.

in response to 357 of these purchase orders.[16] In response to 111 of these purchase orders, Hospira India failed to deliver the amount required.[17] The table below provides but a few examples of Hospira India's failures to supply in 2013:

Purchase Order No. / Product	Quantity Required	Quantity Received	Delivery Date Required	Delivery Date Received
4500423383 / cefazolin inj 1g 25x20ml	33,250	29,400	12/9/2013	7/24/2014
4500432371 / cefepime inj 2g 10x20ml	3,325	2,304	6/17/2013	7/10/2014
4500426412 / cefoxitin inj 1g 25x20ml	2,400	1,392	11/27/2013	1/29/2014
4500395420 / ceftriaxone inj 500mg 10x10ml	3,900	870	1/4/2013	3/14/2013

73. In May 2013, for example, Apotex electronically transmitted from its headquarters in Weston, Florida to Hospira's R&D facility in Chennai, India (1) an 18-month rolling forecast for different quantities, dosage forms, and strengths of cefazolin, cefepime, cefoxitin, ceftriaxone, and pip/taz Products; and (2) purchase orders stating the item number and number of units to be shipped to Apotex in Plainfield, Indiana and billed to Apotex in Weston, Florida. Apotex intended and attempted to market and commercialize these Products in the Territory, *i.e.*, the United States. Apotex engaged in these efforts in accordance with its commercialization responsibilities under the Agreement and the Plan. Certain lots of Hospira's pip/taz Bulk Pack Products were never delivered.

[16] *See, e.g.*, Purchase Order Nos. 4500404815 (Product delivered 480 days late), 4500405116 (Product delivered 407 days late), 4500410217 (Product delivered 465 days late), Ex. 1.

[17] *See, e.g.*, Purchase Order Nos. 4500395420 (shortfall of 3,030 units), 4500400804 (shortfall of 2,200 units); 4500410231 (shortfall of 2,180 units), Ex. 1.

74. Hospira's failure to fulfill Apotex's supply requirements interfered with Apotex's efforts to commercialize the Products and caused Apotex to be unable to fulfill its own obligations to supply its U.S. customers with the Products. As a consequence, Apotex was forced to pay its customers millions of dollars in failure-to-supply penalties.

75. On August 1, 2013, Hospira's Vice President, Karen Blair, wrote to Apotex's then-Associate Director, Global Business Development, Michael Ascenzo, to acknowledge the "penalties that may have been assessed against [Apotex] by GPO's, on tender contracts, etc. due to [Apotex India's] inability to supply Products to them caused by [Hospira's] supply failure. Hospira made no offer to compensate Apotex for these penalties.

76. The year 2014 was no different.[18] Out of the 292 purchase orders Apotex submitted for deliveries to be made in 2014, 192 resulted in late deliveries. Hospira India delivered less than the required amounts in response to 77 purchase orders, highlighted by a shortfall of as large as 8,532 units for one purchase order. Some of these failures are illustrated below:

Purchase Order No. / Product	Quantity Required	Quantity Received	Delivery Date Required	Delivery Date Received
4500460003 / cefazolin inj 1g 25x10ml	14,220	5,688	9/10/2014	10/22/2014
4500458095 / cefoxitin 1g 25x20ml	2,700	1,975	8/20/2014	9/10/2014
4500440960 / ceftriaxone 250mg 10x10ml	14,250	12,650	5/30/2014	7/29/2014
4500463670 / pip/taz 40.5g 300ml	2,700	2,294	10/30/2014	2/3/2015

[18] As an example, Hospira India made late delivery *and* delivered insufficient quantity of Product in response to Apotex's Purchase Order Nos. 4500430842, 4500466988, 4500470471, Ex. 1.

77. Hospira India did not remedy this systematic pattern of non-compliance, and similar untimely and inadequate deliveries persisted in 2015 and 2016.[19] Examples of Hospira India's failures during 2015 and 2016 are listed below:

Purchase Order No. / Product	Quantity Required	Quantity Received	Delivery Date Required	Delivery Date Received
4500473822 / cefazolin inj 1g 25x10ml	12,000	11,623	1/12/2015	2/24/2015
4500505540 / cefazolin inj 10g 10x100ml	5,886	5,722	1/30/2016	1/11/2016 (no delay)
4500476410 / cefepime inj 1g 10x20ml	6,650	3,456	2/27/2015	6/8/2015
4500517145 / cefepime inj 1g 20ml	39,900	19,980	3/30/2016	2/16/2016 (no delay)
4500476394 / ceftriaxone inj 500mg 10x10ml	3,900	2,630	2/27/2015	4/16/2015
4500514860 / ceftriaxone	5,592	5,592 (no shortage)	2/19/2016	3/16/2016
4500480977 / pip/taz inj 40.5mg 300ml	2,700	2,461	3/20/2015	7/28/2015

G. Hospira, Inc. Takes Over The Contract And Supply Failures Continue

78. On February 1, 2017, Hospira India advised Apotex that Hospira, Inc. was taking over responsibilities under the Agreement.

79. On information and belief, Hospira, Inc. is Hospira India's parent entity.

[19] With respect to purchase orders for deliveries in 2015, Hospira India made late delivery *and* delivered insufficient quantity of Product in response to, among others, Purchase Order Nos. 4500482913, 4500486343, 4500499666, Ex. 1. Purchase Orders for deliveries in 2016 suffered the same fate, such as Purchase Order Nos. 4500517145 (shortfall of 19,920 units), 4500514860 (Product delivered 26 days late), Ex. 1.

80. Hospira India remains responsible under the Agreement even after any transfer of responsibilities to Hospira, Inc.

81. The supply deficiencies described herein were compounded by Hospira's failure to seek replacement product from third parties and supply the same to Apotex when Hospira knew or should have known that it could not fulfill Apotex's purchase orders, and/or could not do so timely or fully.

82. Hospira's systematic and continuous failure to meet its supply obligations constitutes a Gross Breach of the Agreement.

83. Hospira's breaches were neither justified nor excused by any provision of the Agreement. To the contrary, they were willful and intentional and designed to undermine Apotex's competitive position in favor of Hospira.

H. Hospira Unfairly Competes With Apotex, Including By Misusing Its Confidential Pricing Information And Breaching Exclusivity Obligations

84. Hospira has sold or otherwise supplied to third parties in the Territory certain drugs that directly compete with Apotex's sale of the Products. Hospira's competitive Products include Maxipime™, a drug manufactured by Hospira at IKKT and sold by it in the Territory in competition with the cefepime Products Hospira is obligated to manufacture for Apotex at the same IKKT facility. Other drugs are third-party manufactured generic versions of the same drugs that Hospira manufactures for Apotex at IKKT, including ceftriaxone, cefazolin, and pip/taz.

85. On information and belief, Hospira acquired the rights to Maxipime™ (the brand version of cefepime), including the rights to sell Maxipime™ in the United States, under an approved New Drug Application, in or around 2012, approximately two years after the Novation. Maxipime™ is listed in the FDA's National Drug Code ("NDC") Directory under the product

NDCs 0409-0217, 0409-0218, 0409-0219, and 0409-0220.[20] Maxipime™ is the "reference listed drug" for all generic cefepime Products marketed in the United States, including the cefepime product that Hospira manufactures for Apotex at its IKKT facility. Orchid and Apotex obtained FDA approval to market cefepime in the United States under an Abbreviated New Drug Application after satisfying the FDA, inter alia, that their cefepime product had been shown to work in the human body in the same way as does Maxipime™. Orchid and Apotex's cefepime product was approved as an AB rated generic of Maxipime™. An AB rating signifies that the generic product is fully and automatically substitutable for the brand product. Thus, when a prescriber writes a prescription for Maxipime™, the pharmacy (except in very limited circumstances) will fill that prescription using a generic version of the drug.

86. After it acquired the rights to Maxipime™, Hospira manufactured it at IKKT, the same facility where it was manufacturing generic cefepime for Apotex.

87. At all times material to this dispute, as more fully set forth below, Hospira sold Maxipime™, and sold or caused to be sold competitive versions of ceftriaxone, cefazolin and pip/taz, in the Territory while it was systematically and continuously failing to supply Apotex's requirements for these very same Products.

88. As further detailed below, Hospira's deliberate decision to divert supply of Products to its own use in competition with Apotex at the very time that it had failed to fulfill its supply obligations under the Agreement was a breach of the Agreement and was done with the intent to and in a manner that willfully injured Apotex, drastically decreasing its competitive position to Hospira's own substantial benefit. Hospira's voluntary decision to close IKKT, the

[20] *See* NDC Directory MAXIPIME, https://www.accessdata.fda.gov/scripts/cder/ndc/dsp_searchresult.cfm (last accessed May 21, 2018).

sole location where it manufactured Product for Apotex, is yet another tactic designed to decrease Apotex's ability to compete against Hospira.

1. Using Underhanded and Unlawful Means, Hospira Displaces Apotex As Market Leader For Cefepime

89. The cefepime family is among the Product Families listed in Exhibit C(1) to the Novation, which Hospira agreed to manufacture exclusively for Apotex for marketing and sale to customers in the United States. In addition to agreeing to manufacture cefepime exclusively for Apotex, Hospira agreed that if it was unable to manufacture sufficient quantities of cefepime for Apotex at IKKT, it would provide replacement product from a third-party source at its sole cost and expense.

90. Hospira is contractually obligated, pursuant to the terms of the Agreement, as amended, to supply Apotex with its cefepime requirements. Despite these agreements, however, since 2012, Hospira has systematically and continuously failed to supply Apotex with Apotex's requirements for cefepime. Examples of cefepime purchase orders that Hospira failed timely to fulfill is included in the spreadsheet attached hereto as Exhibit 1.

91. Hospira's failure to supply Apotex's cefepime requirements was part of a deliberate strategy to sabotage Apotex's ability to commercialize cefepime in the U.S. while simultaneously expanding sales of its competing Maxipime™ product.

92. Publicly available data suggests that Hospira began competing with Apotex by selling Maxipime™ in the United States beginning sometime in 2013, although Hospira began taking steps to undermine Apotex's ability to compete against it even before this.

93. As of January 2013, four generic drug companies had entered the market for cefepime. Apotex was the market leader with 46.17 percent of that market; Sagent Pharmaceutical was second with 30.68 percent; Fresenius Kabi USA was third with 16.07

percent, and Sandoz was fourth with 7.08 percent. Because the brand product is almost always substituted for by the generic product, as would be expected in a mature drug market—and indeed is often required by mandatory generic substitution laws—sales of the brand reference drug (Maxipime™) were negligible.

94. The market for cefepime Products began to change in March 2013. Data indicates that Hospira's Maxipime™ product unexpectedly captured 6.79 percent of the market in that month. Between March of 2013 and December of 2016, the Maxipime™ share of the cefepime market fluctuated, often in lock-step with declines in Apotex's own market share. Thus, in August of 2013, the Maxipime™ share of the market increased to 16.46 percent while Apotex's share declined to 13.48 percent. By April of 2014, the Maxipime™ share had reached 18.26 percent of the market, and it passed 20 percent of the market for the first time in May of 2014. **Remarkably, in August of 2016, Maxipime™ captured 56.68 percent of the cefepime market—more than all generic competitors combined.** For that same month, Apotex's share declined to 0.19 percent of the market.

95. As alleged in more detail below, the declines in Apotex's cefepime market share, and the increases in the market share obtained by Hospira's Maxipime™, coincided with Hospira's systematic failure to fulfill Apotex's requirements for cefepime.

96. During the relevant period, to fill orders for its Maxipime™ product, Hospira manufactured its own cefepime drug – Maxipime™ – at its IKKT facility, while failing and willfully refusing to manufacture cefepime for Apotex, as required by the terms of the Agreement and pursuant to outstanding purchase orders for cefepime issued by Apotex to Hospira in accordance with the terms of the Agreement.

97. Hospira created artificial market demand for its Maxipime™ product by failing and refusing to manufacture cefepime for Apotex at IKKT and by failing and refusing to obtain cefepime for Apotex's product from third party sources. Hospira knew that the effect of its conduct was to create unmet demand at the expense of Apotex because Apotex continuously informed Hospira that its failure to fulfill Apotex's supply requirements was causing Apotex to incur failure to supply penalties.

98. Hospira ensured that it was able to meet the market demand for cefepime created by its conduct by manufacturing Maxipime™ at its IKKT facility, while at the same time failing to manufacture cefepime for Apotex pursuant to its obligations under the Agreement. Hospira's decision to manufacture Maxipime™ rather than cefepime for Apotex at IKKT was a knowing, intentional and willful breach of its obligation to prioritize manufacture of cefepime over the manufacture of Maxipime™. Hospira's decision to divert the supply of cefepime product it manufactured at IKKT to its own use for sale as branded Maxipime™ also was a knowing, intentional and willful breach of its supply obligations under the Agreement.

99. When Hospira ceased manufacturing cefepime for Apotex, Apotex representatives asked Hospira representatives to supply Maxipime™ to Apotex for resale by Apotex, as both the Agreement and the law permit. This is a common and acceptable practice in the industry and is called an "authorized generic." In such circumstances, a brand manufacturer supplies its brand product to a generic company, but the generic label is used on the product. So customers essentially get the exact brand name product at generic prices. Hospira refused.

100. Hospira used Apotex's confidential business information to pursue an unfair marketing strategy to target Apotex's existing and potential cefepime customers and obtain Maxipime™ sales from them at the expense of Apotex. Thus, Hospira solicited Apotex's

contract customers, offering to sell them Maxipime™ in place of the cefepime that Apotex was unable to supply because of Hospira's failure to supply cefepime to Apotex as required by the Agreement. Moreover, although Hospira's Maxipime™ is a "brand" drug normally sold at prices multiples higher than generic substitutes, Hospira offered to sell Maxipime™ to Apotex's customers (and potential customers) at prices on par with or near Apotex's contract pricing for generic cefepime Products. For instance, Hospira approached Apotex's customer NPI and offered to sell it Maxipime™ at a price just above Apotex's cefepime.

101. Hospira was able to target Apotex's customers and priced near Apotex's prices only because Apotex disclosed confidential pricing information about Apotex's cefepime product to Hospira as it was required to under the terms of the Agreement, including Apotex's current and specific average price. This information was intended to assist the parties in pursuing their mutually advantageous commercialization and profit-sharing agreement. The price information is otherwise unavailable to Hospira. Therefore, but for the contract, Hospira would not have had this information and but for its misuse of that information, it could not have priced near Apotex's price when it went after Apotex's clients. Instead, Hospira wrongfully used this information against Apotex as part of its scheme to steal customers from Apotex for its own version of cefepime by removing Apotex from the playing field and then pricing its brand version of cefepime as if it were a generic so customers would leave Apotex for Hospira, as they did.

102. Hospira also intentionally damaged Apotex's goodwill and reputation with its customers, by causing customers to see Apotex as being unable to fulfill its obligations to them – a state of affairs Hospira orchestrated – and then, while it sidelined Apotex – presenting itself to

Apotex's customers as their rescuer – an entity that could supply them with the same product at the same price.

103. Hospira's ability to capture a large share of the cefepime market after the genericization of that market is entirely inconsistent with how such markets ordinarily function. As set forth above, because of generic substitution laws, once generic competition enters a particular drug market, generic products capture virtually the entire market, typically as much as 90 percent of sales after one year. If Hospira had not artificially constricted the supply of generic cefepime and simultaneously marketed its branded cefepime product (Maxipime™) at low generic-like prices, sales of Maxipime™ would have been decimated and captured by generic alternatives because of generic substitution laws, as was happening before Hospira launched its scheme. That Hospira has managed to *increase* its market share in spite of generic competition further demonstrates that something (in fact, Hospira itself) is distorting the market for cefepime.

104. Upon information and belief, including commercially available drug sales data, U.S. sales of Maxipime™ totaled more than $69.46 million between January 2014 and January 2019.

105. Coupled with its failure to supply Apotex with Apotex's cefepime requirements and its decision to devote IKKT's manufacturing capacity to Maxipime™ rather than cefepime, Hospira's U.S. sales of Maxipime™ constitute an intentional and willful breach of the Agreement's exclusivity and non-compete provisions as well as its confidentiality provisions. Hospira's conduct also constitutes fraud and tortious interference with Apotex's existing contracts and prospective relationships. As such, Hospira has committed a Gross Breach pursuant to § 12.2(c)(i) and (iv) of the Agreement.

2. Hospira Has Used And Is Using Similar Improper Tactics To Unfairly Compete With Apotex As To Other Products

106. The pip/taz, ceftriaxone and cefoxitin families were other Product Families listed in Exhibit C(1) or C(2) to the Novation that Hospira agreed to manufacture exclusively for Apotex for marketing and sale to customers in the U.S. In addition to agreeing to manufacture pip/taz, ceftriaxone and cefoxitin exclusively for Apotex, Hospira agreed that if it was unable to manufacture sufficient quantities of these Products for Apotex at IKKT, it would provide replacement product from a third-party source at its sole cost and expense.

107. Hospira is contractually obligated, pursuant to the terms of the Agreement, as amended, to supply Apotex with its pip/taz, ceftriaxone and cefoxitin requirements. Despite this agreement, since 2012, Hospira has systematically and continuously failed to supply Apotex with Apotex's requirements for these Products. A comprehensive list of pip/taz, ceftriaxone and cefoxitin purchase orders that Hospira failed timely to fulfill is included in the spreadsheet attached hereto as Exhibit 1.

108. Hospira's failure to supply Apotex's pip/taz and ceftriaxone requirements was part of a deliberate strategy to sabotage Apotex's ability to commercialize these Products in the U.S. while at the same time expand Hospira's own sales of competing pip/taz and ceftriaxone Products.

109. On information and belief, at all times material to this dispute, Hospira has sold pip/taz and ceftriaxone in the U.S.; and U.S. sales of Hospira's ceftriaxone totaled more than $92.08 million between January 2014 and January 2017.

110. Pip/taz is another product where Hospira has exploited its sidelining of Apotex. While failing to manufacture pip/taz for Apotex, Hospira continued to source pip/taz for itself, Hospira's U.S. sales, according to commercially available drug sales data, totaled $177.15

million between January 2014 and January 2017. Hospira currently sits on tens of open orders for certain popular strengths of pip/taz, which Apotex is unable to obtain from any other source. While Hospira could use the pip/taz it has sourced for itself to meet Apotex's needs, it has not done so. Instead, it has exploited Apotex's absence from the market to increase its own sales and those of its parent, Pfizer. **Today, commercially available sales data show Pfizer selling $393,000,00 of pip/taz annually as of January 2019. Apotex's annual sales, by comparison, were $774,823.** This was despite Hospira's duty to prioritize providing pip/taz product to Apotex. Moreover, Hospira compounded its failure to provide pip/taz by lying to Apotex about this, telling Apotex representatives it could not manufacture pip/taz at IKKT because of the possibility of contamination with cefepime, when in fact it was able to and did on other occasions manufacture pip/taz there.

111. Hospira created market demand for competing pip/taz and ceftriaxone Products by failing and refusing to manufacture these Products for Apotex at IKKT. Hospira knew that the effect of its conduct was to create unmet demand at the expense of Apotex because Apotex continuously informed Hospira that its failure to fulfill Apotex's supply requirements was causing Apotex to incur failure-to-supply penalties chargeable to Hospira.

112. Hospira ensured that the market demand for pip/taz and ceftriaxone created by its improper failure to supply Apotex was met. Hospira sourced these Products from third parties and directly sold them in the U.S. As Hospira did so, it failed to prioritize Apotex's supply needs and failed to fill Apotex's unfilled orders with that same source of supply, as it was required to do under the Agreement.

113. Hospira engaged in similar unfair competition with respect to the cefazolin product family. As with the other Shared Profit Drugs alleged above, beginning January 2012,

Hospira violated the Agreement by systematically and continuously failing to supply Apotex with Apotex's requirements for cefazolin, as reflected in Exhibit 1 hereto. While cefazolin was an Existing Competing Product that could be sold to a limited number of Permitted Customers, Hospira increased sales of cefazolin Products to Permitted Customers (in this case, Hospira itself and Sandoz) by failing to fulfill Apotex' cefazolin requirements. Hospira artificially and anti-competitively restricted market supply and created unmet market demand that Apotex would otherwise have filled. By restricting competitive sources of supply for these Permitted Customers, Hospira increased the likelihood that these Permitted Customers would take larger quantities from Hospira to fulfill unmet demand artificially created by Hospira's wrongful conduct and, on information and belief, they did.

114. In an effort to secure an even larger market share at Apotex's expense, upon information and belief, Hospira improperly sold cefazolin to Permitted Customers at a price that was lower than what the parties had agreed to for such sales, in violation of § 5 of Amendment No. 2 to the Agreement (as incorporated in Novation § 1(I)). Hospira also failed to pay royalties to Apotex, in whole or in part, for such sales of cefazolin to Permitted Customers, in violation of Section 6 of Amendment No. 2 to the Agreement (also as incorporated in Novation § 1(S)).

115. Commercially available drug sales data evidences that sales by Hospira of cefazolin Products in the U.S. totaled over $27.01 million between January 2014 and January 2017, and sales by Sandoz of cefazolin Products in the U.S. totaled more than $32.36 million between January 2014 and January 2019.

116. Hospira's decision to use the third-party supply of pip/taz, ceftriaxone and cefazolin in competition with Apotex rather than to use it to fill Apotex's unfilled orders was a

knowing, intentional and willful breach of its obligation to prioritize Apotex supply requirements over its own requirements.

117. Hospira used Apotex's confidential business information to obtain, directly and/or indirectly, sales of pip/taz, ceftriaxone, and cefazolin at the expense of Apotex. Thus, Hospira solicited, and/or caused others to solicit, Apotex's contract customers, and directly or indirectly sold to these customers pip/taz, ceftriaxone, and cefazolin Products in place of Apotex, knowing that Apotex could not fill its customers' orders for these Products because of Hospira's failure to supply these Products to Apotex as required by the Agreement. Hospira was able to target, directly and/or indirectly, Apotex's customers and match Apotex's prices only because Apotex disclosed confidential pricing information about Apotex's pip/taz, ceftriaxone, and cefazolin Products to Hospira as it was required to under the terms of the Agreement, including specific, then-current average price information. This information was intended to assist the parties in pursuing their mutually advantageous joint commercialization and profit-sharing agreement. Instead, Hospira wrongfully used this information against Apotex as part of its scheme to evade its contractual obligations and compete directly or indirectly against Apotex with competing versions of pip/taz, ceftriaxone, and cefazolin.

118. Hospira's conduct involving the failure to supply and/or sale of competitive pip/taz, ceftriaxone, cefoxitin and cefazolin Products constitutes both a breach of the Agreement's exclusivity and non-compete provisions and fraud. As such, Hospira has committed Gross Breaches, pursuant to § 12.2(c)(i) and (iv) of the Agreement.

I. Hospira's Failures In Operating IKKT Lead To An FDA Shutdown Which Causes Additional Harm To Apotex

119. More recently, Hospira's supply failures have been exacerbated by its inability to provide any pip/taz, cefoxitin, cefazolin and ceftriaxone Products to Apotex due to regulatory

issues. The FDA conducted an audit of Hospira's IKKT plant from March 27 to April 3, 2018, during which it found numerous issues with Hospira's manufacturing practices. Following that audit, Hospira stopped all manufacturing and production processes at its IKKT plant, and suspended the release of any Products currently in stock at the plant. As a result, Hospira has not fulfilled Apotex's orders for cefazolin, cefepime, ceftriaxone, cefoxitin and pip/taz and, even if it kept IKKT open, would not be able to fulfill these orders from its own manufacturing facility for the foreseeable future.

120. In addition to its failure to fulfill current orders and inability to fulfill future orders, Hospira had informed Apotex that Hospira would issue a recall for one or more of the Products at issue previously supplied. That recall process has imposed and will impose significant expenses upon Apotex: (1) Apotex has and will incur administrative expenses associated with complying with the recall; and (2) Apotex has and will incur costs associated with the return of the recalled Products and for storing such Products. Hospira has compounded the harm from this by forcing Apotex to incur costs for a recall that is entirely due to Hospira's own shortcomings.

121. As detailed below, despite that the manufacturing and production of Apotex's Products has been stalled for some time, while IKKT remained open there was at least the possibility that production would resume in the future. Now, with Hospira's abrupt decision to close the plant, Hospira has destroyed this possibility. Because Apotex is unable to obtain certain of these Products from any other source and because Hospira has not agreed to source replacement product for Apotex from third parties, the effect of Hospira's voluntary closing is to eliminate Apotex as a competitor for these Products as well.

J. Hospira Misrepresents Present Facts To Apotex As Part Of Its Sabotage Of Apotex's Efforts to Commercialize the Products

122. Employees of Hospira and Apotex were in regular contact with one another at all times relevant to this action and communicated at least weekly either by phone or by email about the supply issues described above.

123. From 2011 through 2016, Gina Bahou of Apotex managed the day-to-day operational components of the relationship between Hospira and Apotex.

124. From 2010 through 2016, Michael Ascenzo of Apotex was responsible for managing the business relationship between Apotex and Hospira.

125. During the relevant time, both Ms. Bahou and Mr. Ascenzo were in regular communication by telephone and email with their counterparts at Hospira, including Mr. Kannan Venkatesan, Mr. Kabilan Alagiri, and Ms. Nikitha Suresh.

126. From 2011 through 2016, Apotex and Hospira conducted bi-weekly or weekly telephonic meetings to discuss the status of the relationship, including the status of manufacturing operations at IKKT, pending orders, unfilled orders, and other supply issues. Ms. Bahou participated in each of these meetings for Apotex. Depending upon the time frame, either Mr. Alagiri or Ms. Suresh participated in these meetings on behalf of Hospira. From time to time, Ms. Bahou communicated directly with Mr. Venkatesan as well, either during one of these meetings or otherwise.

127. Because Hospira was consistently behind on its obligations to fulfill Apotex's pending purchase orders, these weekly meetings were routinely devoted to discussing the status of the outstanding orders, Hospira's willingness and ability to fulfill these orders, and Hospira's assurances about the efforts it was making to identify and obtain alternative sources of supplies for the Products it had failed to supply.

128. During each of these meetings, and from time to time in email, Mr. Alagiri and/or Ms. Suresh attributed the supply problems to technical and/or manufacturing issues, to API supply problems, and/or to financial difficulties. Mr. Alagiri and Ms. Suresh assured Ms. Bahou that Hospira was using its best efforts to resolve the manufacturing issues, that Hospira was seeking alternative sources of supplies but that Hospira had not been successful in doing so, and that Hospira was fully committed to the parties' joint development efforts under the Agreement. None of this was true. From time to time, Mr. Venkatesan made representations materially identical to those made by Mr. Alagiri and Ms. Suresh.

129. Between 2010 and 2017, Mr. Ascenzo regularly communicated with Mr. Venkatesan about the business relationship between Apotex and Hospira. These communications occurred on an ad hoc basis as necessitated by developments in the relationship. Most of the communications involved issues relating to Hospira's failure to fulfill Apotex's requirements for the Products. During each of these conversations, Mr. Venkatesan attributed the supply problems to technical and/or manufacturing issues, to API supply problems, and/or to Orchid's alleged financial difficulties. Mr. Venkatesan assured Mr. Ascenzo that Hospira was using its best efforts to resolve the manufacturing issues, that Hospira was seeking alternative sources of supplies but had not been successful in doing so, and that Hospira was fully committed to the parties' joint development efforts under the Agreements. None of this was true.

130. In fact, Hospira was not committed to the parties' joint development efforts. Nor was Hospira using its best efforts to remedy its manufacturing issues and/or find alternative sources of supply to fulfill Apotex's unfilled orders. Rather, as described above, Hospira had decided to compete with Apotex, and elected to engage in this competition by, among other

things, withholding supply of the Products from Apotex while simultaneously using Apotex's confidential business information – including pricing information – to cause Apotex's existing and prospective customers to buy Hospira's competing Products instead of Apotex's sidelined Products.

131. Despite Hospira's contract obligation to find replacement product to fulfill Apotex's outstanding purchase orders, Hospira never complied with its contractual obligation to do so, and instead, used product acquired from third parties to compete with Apotex.

132. At no time did either Mr. Alagiri, Ms. Suresh or Mr. Venkatesan or any other Hospira employee ever inform Ms. Bahou that Hospira was using Apotex's confidential information supplied under the Agreement to compete with Apotex.

133. In 2013, Apotex discovered that Hospira was manufacturing Maxipime™ at its IKKT facility – a fact Hospira had not disclosed – at the same time as Hospira was failing to fulfill Apotex's requirements for cefepime, cefoxitin, ceftriaxone, cefazolin and/or pip/taz and telling Apotex that this was due to technical and manufacturing issues at IKKT. Because of this discovery, Apotex asked for a meeting with Hospira to discuss these issues.

134. The meeting occurred at Apotex's offices in Toronto, Ontario, Canada on July 17, 2013. Apotex was represented at the meeting by Michael Ascenzo, Gina Bahou, Peter Eichinger, and Erin Organ. David Powell and Kannan Venkatesan attended on behalf of Hospira.

135. At the meeting, Mr. Powell and Mr. Venkatesan made a presentation to Apotex addressing the outstanding supply issues and distributed a power point presentation to all attendees. Among other things, Hospira blamed its supply problems on issues related to its API supplier, Orchid, and to issues at IKKT. Hospira acknowledged that it was manufacturing Maxipime™ at IKKT, but refused Apotex's demand that it used its manufacturing capacity to

manufacture cefepime or any other of the Products. Hospira instead advised Apotex that it was actively seeking alternate sources of supplies to fill Apotex's unfilled orders when this was false. Hospira's representatives did not disclose that Hospira had already obtained alternative sources of supply for each of these Products, and despite Hospira's obligation to find replacement product to fill Apotex's purchase orders, Hospira never did so and, instead, it used these third-party sourced Products to compete with Apotex while armed with Apotex's confidential information.

136. Apotex and Hospira conducted follow-up meetings in October, November and December of 2013. Ray Coates, Stan Chomrak, Derick Gene, Michael Ascenzo, Jeff Hampton, Gina Bahou, Erin Organ, and Peter Eichinger each attended certain of these meetings on behalf of Apotex. Mr. Rob Rathman and Mr. Venkatesan attended on behalf of Hospira. At these meetings, Hospira made representations like those made at the July 2013 meeting. In the October and/or November meeting(s), Apotex specifically requested that Hospira supply it with its Maxipime™ product. While, as noted above, this is a common and accepted practice and while the request was consistent with Hospira's duty to prioritize sourcing Product for Apotex, Hospira refused.

K. Apotex Has Already Suffered Hundreds Of Millions Of Dollars Of Harm

137. Because of Hospira's Gross Breaches of the Agreement and other misconduct described above, Apotex has suffered, and continues to incur, significant expenses, losses, and damages.

138. Apotex incurred millions of dollars in failure-to-supply ("FTS") penalties and/or service level commitment ("SLC") penalties from customers Apotex could not supply because of Hospira's misconduct many of whom Hospira itself supplied instead. These customers included

regional and national accounts operating in nearly every class of trade—*e.g.*, long-term care facilities, pharmaceutical wholesalers and distributors, group purchasing organizations, and specialty infusion services providers.

139. Apotex's business relationships with these existing customers and prospective customers were harmed by Hospira's Gross Breaches of the Agreement and other intentional and willful misconduct resulting in loss of goodwill, reputational harm, and lost opportunity costs.

140. In addition to FTS/SLC penalties, Apotex incurred millions of dollars in added shipping costs. Between April 2015 and March 2016 alone, for example, Apotex paid upward of $1.2 million for 105 air shipments of Products. Because of Hospira's recurring (and ongoing) shipping delays, Apotex has paid at least $6 million to expedite Product shipments from IKKT to the United States for domestic distribution.

141. To avoid incurring additional penalties and costs due to Hospira's inconsistent supply, Apotex was forced to reject numerous bids for Products from prospective customers. Between April and September 2016, for example, Apotex rejected more than $72 million in bids.

142. Apotex has not been fully compensated by Hospira for the FTS/SLC and other penalties it has incurred. Nor has Hospira repaid the millions of dollars Apotex spent responding to Hospira's supply failures and routine delays. Finally, Hospira has refused to compensate Apotex for the business lost as a result of bids rejected for inability to sell, or business lost because of Hospira's own conduct in the marketplace.

143. Hospira's intentional and willful acts also drastically decreased Apotex's ability to compete, causing it to suffer a significant loss of business due to Hospira's misconduct. Apotex's market share declined precipitously while Hospira's soared. Hospira thus reaped profits that rightfully belonged to Apotex, an amount of at least hundreds of millions of dollars.

L. Apotex Attempts to Mitigate Its Damages

144. Despite Hospira's repeated and continuous failure to meet its supply obligations under the Agreement, Apotex worked closely with Hospira to manage the supply issues within the context of the parties' Agreement. Apotex was lulled by Hospira's representatives into believing that Hospira was acting in good faith to remedy the supply issues, including by resolving issues at the IKKT plant or to obtain the supply of Products from third parties.

145. However, even before it became clear that Hospira was engaging in fraud as to Apotex, it became evident to all parties that Hospira would not remedy the supply issues, either because it could not (despite assurances to the contrary) or because it simply would not. (And Hospira's unilateral decision to close IKKT confirms the latter).

146. As was its right under the Agreement, Apotex determined that it was in the best interests of all parties to the Agreement, including Hospira, for Apotex to attempt to mitigate the losses it was suffering as a result of Hospira's breaches of the Agreement. As a result, Apotex commenced a search for alternative suppliers of the Products subject to the Agreement. Apotex elected to seek alternative sources of supply for these Products only because of Hospira's breaches and solely in an effort to mitigate the damages it was suffering as a result of these breaches.

147. Obtaining alternative suppliers for drug Products manufactured for distribution in the United States is a complex and time-consuming undertaking, in part because of regulatory requirements established by the FDA. For example, any new supplier must be qualified under applicable regulations before drug Products manufactured by the new supplier may be distributed by Apotex in the United States.

148. Eventually, Apotex identified Qilu as a potential supplier for certain of the Products subject to the Agreement. After engaging in appropriate due diligence, Apotex arranged for Qilu to serve as an alternative supplier of the following Products: pip/taz powder for injection, cefazolin powder for injection, cefepime powder for injection, and ceftriaxone powder for injection.

149. Apotex eventually stopped ordering some of the Products at issue from Hospira, as reflected in the rolling forecasts that Apotex submitted to Hospira.

150. Apotex continued, however, to purchase other pip/taz and cefoxitin Products from Hospira under the terms of the Agreement, as well as the 10-gram strengths of cefazolin, and is unable to source these through Qilu. Hospira's supply problems continued. As described above, however, following the FDA's identification of Hospira's shortcomings at IKKT in the audit that concluded on April 3, 2018, Hospira shut down all manufacturing and production at its IKKT facility (the manufacturing plant at which Hospira manufactures pip/taz and all of the other Products subject to this Agreement). Hospira since that date therefore has ceased to supply Apotex with any of the drugs subject to the Agreement, including pip/taz, cefoxitin and cefazolin (10g strength). Now with the Plant closing, those supply failures will become permanent, and Apotex will be effectively excluded from competing in these markets.

M. Hospira Announces The Closing Of IKKT, Making No Provision To Fulfill Obligations To Apotex

151. Having weakened Apotex as a competitor through the misconduct described above, Hospira now attempts to deliver the coup de grace to its rival. It is closing IKKT, the sole plant where it has manufactured Products for Apotex. The closing will leave Apotex unable to obtain certain drugs for which Apotex has no other source. That this is precisely the result Hospira seeks to obtain is demonstrated by its further refusal to source replacement product

through third parties, despite its contractual obligation to do so. Because Hospira, on information and belief, continues to maintain supply of its rival drugs, the shuttering of IKKT appears a continuation of its strategy to eliminate the competition and steal customers and market share.

152. On January 9, 2019, Hospira, through its counsel, advised Apotex of this closing. (*See* Letter from A. Reyes to J. Matthews, dated Jan. 9, 2019 (the "January 9 Letter") attached hereto as Ex. 2.)

153. Hospira made the decision to close IKKT electively and unilaterally.

154. The January 9 Letter did not acknowledge (or dispute) Hospira's ongoing obligation to Apotex. It did not commit to provide Apotex with product going forward or explain how it would manufacture or source product in the future.

155. The closing represents a sea-change for Apotex. While Hospira has not supplied Product for some time, there remained the possibility that Hospira would once again manufacture Product after it remedied the shortcomings identified by the FDA. Now Hospira has foreclosed that possibility.

156. As noted above, it is a complex, labor-intensive and time-consuming process to find another party which can manufacture product for Apotex that meets regulatory standards.

157. Because of Hospira's silence about its duties to Apotex, Apotex, through counsel, wrote Hospira's counsel to demand that Hospira either manufacture Product for Apotex itself or immediately identify a third party source to do so. (*See* Letter from J. Matthews to A. Reyes, dated Jan. 13, 2019, attached hereto as Ex. 3).

158. Hospira, through counsel, responded but still failed to acknowledge any obligations to Apotex or provide any plan for performance. (*See* Letter from A. Reyes to J.

Matthews, dated Jan. 21, 2019, attached hereto as Ex. 4). Hospira did not agree to source replacement product through third parties. Instead, it treated Apotex's request as solely backward-looking. Even as to these, Hospira purported not to know about open purchase orders Apotex has already submitted to Hospira but which Hospira made no effort to fill (and there are 55 of these). Nor did Hospira acknowledge the numerous other orders where Hospira shipped Product to Apotex, only to order Apotex not to distribute this to its customers because an FDA recall issued due to Hospira's shortcomings, rendering these orders useless and effectively unfulfilled. Instead, Hospira noted that Apotex had sourced certain Product from Qilu, suggesting this somehow excuses Hospira's obligations as to past and future performance and ignoring its knowledge (from Apotex's First Amended Complaint, if not otherwise) that there was only a limited subset of Products Apotex could source from Qilu and that it still depends on Hospira for others. Hospira also accused Apotex of a "Gross Breach" under the Agreement by sourcing any Products through Qilu. That threat is just another anticompetitive tactic designed to intimidate Apotex and keep it out of the market. Thus, when Apotex asks Hospira to supply Products as the Agreement requires, Hospira refuses, keeping Apotex out of the market. When Apotex then actually goes out and covers for certain products, Hospira threatens to sue over this, in the hopes of intimidating Apotex from competing. Either way, Hospira tries to unfairly shed its competition. The closing of IKKT demonstrates even more strongly that Apotex appropriately sought to obtain alternative suppliers for the Products subject to the Agreement. Apotex would have been utterly ejected from the U.S. market as to all Products, solely as a result of Hospira's conduct, had it not obtained an alternative supplier for the subset of Products it could.

159. Apotex then advised Hospira of open orders, (*see* Letter from J. Matthews to A.

Reyes, dated Jan. 24, 2019, attached hereto as Ex. 5), yet Hospira continued to refuse to source replacement product from third parties or to otherwise honor its ongoing commitments under the Agreement, (*see* Letter from A. Reyes to J. Matthews, dated February 5, 2019, attached hereto as Ex. 6), exposing its prior request for open order information as an empty gesture and stall tactic. While Apotex emphasized this to Hospira, (*see* Letter from J. Matthews to A. Reyes, dated Feb. 25, 2019, attached hereto as Ex. 7), the fact remains that approximately seven months have now passed since Hospira announced its closing, yet, despite repeated requests from Apotex (and its contractual duties), and while claiming it is considering the issue,[21] it offers no plan for satisfying its ongoing obligations under the Agreement going forward.

160. Apotex now faces devastating losses and further injury in its ability to compete as a result of the closing.

161. Hospira either has not tried to remedy the problems at IKKT or has tried and failed.

N. <u>Apotex Engages Hospira in Dispute Resolution Efforts</u>

162. Section 19.9 of the Agreement sets forth the mechanisms for addressing disputes arising from or relating to the subject matter of the Agreement, including Gross Breaches. It directs the parties to

> endeavor to resolve in good faith any disputes or conflicts, failing which the Parties shall first submit such conflict or dispute to the [Executive Management Committee ("EMC")] for resolution. If the EMC is unable to resolve the resolution with ten (10) business days thereafter (or such other time as may be mutually agreed upon), the conflict shall be referred to the respective Chief Executive Officers for formal negotiation and resolution . . . .

[21] *See* Letter from A. Reyes and J. Matthews dated April 15, 2019, attached hereto as Ex. 8 (noting, *inter alia*, that Hospira "does not concede that Apotex is in fact entitled to replacement product under the Agreement.")

Agreement § 19.9(a).[22] "If the matter remains unresolved thirty (30) business days thereafter (or such other time as may be mutually agreed upon), the conflict shall be submitted to arbitration . . . ." *Id.*

163. Article 19 is clear, however, that "[a] party is not required to submit Gross Breaches to arbitration." *Id.* § 19.9(a)(i) (emphasis added). A "Gross Breach" is defined in pertinent part in the disjunctive as a (i) "[b]reach of exclusivity, that is, a willful, knowing or intentional breach of a material provision of Article 7 of this Agreement"; (ii) "systematic and consistent failure by [Hospira] to meet its supply obligations in such a manner that Apotex is denied the benefit of its bargain hereunder"; or (iii) "[w]illful, knowing or intentional fraud of any nature." *Id.* § 12.2(c) (i), (ii), and (iv).

164. Between June 2017 and March 2018, Apotex engaged Hospira in a good-faith effort to resolve Gross Breaches and other misconduct alleged herein as required by § 19.9 of the Agreement.

165. Apotex exhausted the informal dispute resolution steps of § 19.9, prompting Apotex to commence the present action.

V. FRAUDULENT CONCEALMENT AND TOLLING OF LIMITATIONS PERIODS

166. Hospira has concealed from Apotex the details of its breaches of contract, fraud and unfair and deceptive acts and practices during the time Hospira engaged in that conduct so as to avoid detection and cessation of its ill-gotten profits and benefits.

167. Given Hospira's concealment of the unlawful conduct, including but not limited to its express misrepresentations to the contrary, Apotex had no way of knowing that Hospira

[22] The EMC's composition and functions are described in Article 8 of the Agreement.

was engaging in such conduct to its detriment, or of any facts that might have led to the discovery thereof in the exercise of reasonable diligence.

168. By reason of the foregoing, Apotex's claims are timely under any applicable statute of limitations (as tolled by the filing of this Complaint) pursuant to the doctrine of fraudulent concealment.

VI. COUNTS

COUNT I
(Monopolization)

169. Apotex realleges and incorporates by reference paragraphs 1 through 168 of this Complaint.

170. The relevant product market is that for the drug cefepime, including branded and AB rated generic products.

171. Apotex's cefepime is an AB rated generic equivalent to Hospira's cefepime drug Maxipime™ and they are functionally interchangeable. Generic substitution laws mean that generic cefepime would ordinarily be substituted for branded cefepime if the generic is available.

172. The relevant geographic market is the United States.

173. Hospira has possessed monopoly power in the relevant market. As of August 2016 it had 56.58 percent share of the cefepime market.

174. There are only four other participants in the cefepime market, each with limited share and there is low elasticity of demand, in that the demand for cefepime vis-à-vis other drugs is generally not sensitive to changes in other economic variables such as price. There are no products which are interchangeable or substitutable for cefepime.

175. There are significant barriers to enter the cefepime market, including the need to obtain regulatory approvals and the limited availability of manufacturing facilities equipped and authorized to manufacture cefepime.

176. Hospira intentionally and willfully acquired and maintained monopoly power in cefepime through an array of tortious acts, and other misconduct described above including, but not limited to:

a. continuing to manufacture Maxipime™ at IKKT while halting all manufacturing of Apotex's cefepime Product;

b. refusing to source cefepime for Apotex from third parties thereby choking off Apotex's supply of cefepime and leaving it unable to serve its customers;

c. tying up third-party sources of cefepime for itself;

d. approaching Apotex's customers while Apotex was unable to serve them (solely because of Hospira's conduct) and then offering them Maxipime™ at a price on par with or near Apotex's contract price, a price it only knew through confidential information Apotex disclosed pursuant to the Agreement;

e. selling Maxipime™ as if it were a generic rather than the branded drug it is; and

f. preventing Apotex from accepting bids from prospective customers.

177. Hospira took these abrupt and damaging anti-competitive actions against Apotex despite the fact that Hospira had previously enjoyed a profitable relationship with Apotex and used Apotex's capital investments to develop its IKKT facility.

178. As a result of this misconduct, Hospira's cefepime market share soared from negligible to a majority market share, becoming market leader, while Apotex's correspondingly plummeted, falling from market leader to a negligible share.

179. Hospira did not gain monopoly power as the result of a superior product, business account or historic accident.

180. By intentionally excluding its primary competitor by anti-competitive means, Hospira has injured the competitive process in the market for cefepime. After excluding Apotex Hospira approached Apotex's customers and priced Maxipeme™ below what it would have had it been priced had it been sold as a brand product but just higher than Apotex was charging, leading consumers to pay higher prices.

181. Apotex has suffered injury as a result of Hospira's unlawful acquisition and abuse of monopoly power.

COUNT II
(Attempted Monopolization)

182. Apotex realleges and incorporates by reference paragraphs 1 through 181 of this Complaint.

183. Hospira engaged in predatory and anti-competitive behavior in an effort to gain monopoly power as to cefepime, as described above.

184. Hospira engaged in that same behavior in an effort to monopolize the individual product markets for the other Products which are subject to the Agreement, including ceftriaxone and cefazolin. These markets include branded and generic Products that are AB rated against the branded products. The geographic market for these Products is also the United States.

185. For each of these Products, there is low elasticity of demand for consumers and there are no products which are functionally interchangeable.

186. The same barriers to entry to the cefepime market exist for the markets of these other drugs.

187. Hospira's decision to close IKKT is another example of predatory and anti-competitive conduct, as it is wholly voluntary on the part of Hospira and denies Apotex any possible source for the Products it cannot obtain from Qilu.

188. Specific intent to monopolize is indicated by Hospira's misuse of confidential Apotex customer pricing information, as well as other information Apotex was required to provide under the Agreement with regard to each of these Products, which enabled Hospira to target Apotex's customers and undercut Apotex on price.

189. Hospira's specific intent to monopolize is further shown, *inter alia*, by its refusal to source replacement Products from third parties and its closing of IKKT, which means that Hospira will eliminate Apotex as a competitor in the markets for cefoxitin and certain pip/taz Products.

190. There is at least a dangerous probability that Hospira will successfully monopolize the cefepime market. Indeed, it already reached monopoly-level shares of that market.

191. Hospira's market share for ceftriaxone-- which rose to 43.75% as of January 2017-- and cefazolin-- which rose to 30.76% as of January 2016--evidences a similarly dangerous probability that it will be successful in monopolizing the markets for those Products.

192. Apotex has been injured by Hospira's attempted monopolization.

COUNT III
(Breach of Contract)

193. Apotex realleges and incorporates by reference paragraphs 1 through 192 of this Complaint.

194. The Agreement between Apotex and Orchid and, following execution of the Novation, between Apotex and Hospira, created legally enforceable rights and obligations.

195. To the extent not thwarted by Hospira's Gross Breaches, Apotex has at all times performed and fulfilled its purchase, commercialization, and other obligations under the Agreement.

196. Hospira breached the Agreement by, *inter alia*, (i) making some or all of the Products available to third parties in the Territory (in violation of §§ 1(J) and 5 of the Novation); (ii) systematically and consistently failing to timely supply Apotex with Product in the quantities specified in Apotex's purchase orders (in violation of Article 5 of the Agreement as amended by the Novation); (iii) secretly using Apotex's confidential business information to compete with Apotex by communicating with and offering Products to Apotex's customers at lower prices (in violation of Article 18 of the Agreement and § 4 of the Novation); (iv) selling cefazolin Products to Apotex competitors which were Permitted Customers under the Agreement at prices lower than required by Amendment No. 2 to the Agreement, and failing to pay royalties, in whole or in part, due to Apotex from such sales (in violation of § 1(I) of the Novation); (v) failing to prioritize to supply Apotex (in violation of § 1(E) of the Novation); (vi) failing to obtain alternative sources from third parties when it could not manufacture sufficient Product to supply Apotex (in violation of § 1(H) of the Novation); (vii) entering into contracts, commitments or agreements that impaired or inhibited Hospira's ability to perform its obligations under the Agreement (in violation of § 14.2(a) of the Agreement), and (viii) refusing to source replacement products or manufacture products on its own despite announcing it is closing the IKKT plant, in violation of §§1.36 and 4.1 of the Agreement and the Novation.

197. Apotex has sustained and continues to sustain economic and noneconomic damages as a result of Hospira's breaches of the Agreement.

COUNT IV
(Florida Deceptive and Unfair Trade Practices Act – Damages)

198. Apotex realleges and incorporates by reference paragraphs 1 through 197 of this Complaint.

199. Section 501.204(1) of FDUTPA declares unlawful "[u]nfair methods of competition, unconscionable acts or practices, and unfair or deceptive acts or practices in the conduct of any trade or commerce."

200. At all times relevant hereto, Apotex was and is a consumer pursuant to FDUTPA § 501.203(7).

201. At all times relevant hereto, Hospira was and is a person or entity engaged in "trade or commerce" pursuant to FDUTPA §501.203(8).

202. Hospira violated § 501.204(1) of FDUTPA by engaging in unfair methods of competition and unfair and deceptive acts or practices, the impact of which substantially occurred in the State of Florida and/or caused harm to Apotex in the State of Florida and elsewhere.

203. In particular, Hospira willfully used opportunities it only gained under its contract with Apotex to unfairly compete against it and to capture Apotex' market share in Florida and throughout the United States, at least with respect to the Existing Competing Products and Products comprising the cefepime, ceftriaxone, cefazolin, and pip/taz product families. For example, Hospira converted Apotex's trade secrets (the highly sensitive pricing information Apotex furnished to Hospira in accordance with the profit sharing arrangements in the Agreement and other highly confidential information about customers and customer demand)

and used those secrets against Apotex in competition with Apotex by "price-matching" or undercutting Apotex's prices in the market. Hospira also continued to manufacture its own cefepime product at IKKT, while now manufacturing Apotex's product, which was supposed to receive priority. Hospira also tied up alternative third party manufacturing sources for itself ensuring they were not available for Apotex. And Hospira lied to Apotex about its present activity, leading Apotex to believe it was trying to resolve manufacturing issues at IKKT and find third party sources, when it was not. This was intended to and had the effect of lulling Apotex into continuing to rely on Hospira as its exclusive source and not seek a third party supplier. Now, Hospira is closing IKKT, leaving Apotex unable to compete as to certain of the Shared Profit Drugs, including strengths of pip/taz and cefoxitin.

204. Hospira's communications (including its misrepresentations) reached and were relied upon by Apotex's marketing and sales operations in Florida.

205. Apotex has sustained and continues to sustain actual damages and competitive harm because of Hospira's violations of FDUTPA.

VII. PRAYER FOR RELIEF

WHEREFORE, Apotex prays for judgment against Hospira that:

1. Hospira be required to pay to Apotex the following:

    a. In accordance with the common law of the State of New York, direct damages, restitution and disgorgement of profits, lost profits from business interruption, royalties owed and other special or indirect damages and losses Apotex sustained as a natural and probable consequence of Hospira's misconduct, including punitive damages in a sum sufficient to deter future wrongdoing.

b. In accordance with Fla. Stat. § 501.211, actual damages plus attorneys' fees and court costs as provided in § 501.2105, as well as punitive damages to the extent permitted under §§ 501.201 *et seq.* in a sum sufficient to deter future unlawful acts and practices.

c. In accordance with Section 4 of the Clayton Act, 15 U.S.C. § 15, treble damages, plus costs and attorney's fees for Hospira's antitrust violations.

2. Awards Apotex such other and further relief as the Court deems just and equitable, including but not limited to attorneys' fees and costs.

VIII. DEMAND FOR JURY TRIAL

Apotex hereby demands a trial by jury on all issues so triable.

Dated: Boston, MA
July 26, 2019

Respectfully submitted,

FOLEY & LARDNER LLP

By: */s/ James W. Matthews*

James W. Matthews (admitted pro hac vice)
Foley & Lardner LLP
111 Hungtington Avenue, Suite 2500
Boston, MA 02199-7610
Tel: (617) 342-4000
jmatthews@foley.com

David B. Goroff (admitted pro hac vice)
Foley & Lardner LLP
321 N. Clark Street, Suite 2800
Chicago, IL 60654-5313
dgoroff@foley.com

Sara P. Madavo
Foley & Lardner LLP
90 Park Avenue
New York, New York 10016
Telephone: (212) 338-3626
Facsimile: (212) 682-2329
smadavo@foley.com

Attorneys for Plaintiff Apotex Corp.

CERTIFICATE OF SERVICE

I hereby certify that on the 26th day of July, 2019, I served a copy of Plaintiff Apotex Corp.'s Second Amended Complaint on the counsel of record by Electronic Case Filing (ECF).

/s/ James W. Matthews
James W. Matthews